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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,367	03/10/2004	Janel E. Young	ETH5095CIP	4470

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EXAMINER	
FUBARA, BLESSING M	
ART UNIT	**PAPER NUMBER**
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/797,367	YOUNG ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19,21-25,37 and 39-41* is/are pending in the application.

4a) Of the above claim(s) *1-13,17-19 and 35-37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-16, 21-34 and 39-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of response to restriction requirement, preliminary amendment and remarks filed 10/29/07. Claims 20, 26 and 38 are canceled. Claim 21 is amended. Claims 1-19, 21-25, 27-37 and 39-41 are pending.

Election/Restrictions

1. Applicant's election of claims 14-41 of Group II in the reply filed on 10/29/07 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Applicant has also elected a burst release and a barrier as the form of the delivery vehicle. Also, claims 20 and 38, which are directed to absorbable barrier are canceled; claim 26 directed to burst or sustained release is also canceled. Claims reading on the elected barrier are 15, 21 and 39. Thus claims 17 -19, 35-37 that recite liposome and solution as the carrier vehicle forms are withdrawn. Claims 1-13 are withdrawn from consideration in view of the election of Group II. Therefore, claims 1-13, 17-19 and 35-37 are withdrawn. Claims 14-16, 21-25, 27-34 and 39-41 are examined, with claim 21 included because, though dependent from claim 19 recites a barrier.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 14-19, 21-25, 27-37 and 39-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 14, 24-26, 28 and 31-33 recite "analog" of Tranilast and the boundaries for the protection sought for analog of Tranilast by the applicant are not discernible making the scope of the claims unclear and indefinite.

Claim 39 is indefinite because it depends on cancelled claim 38. However, claim 39 is examined as being dependent on claim 29.

However, in this wise, claim 38 recites the limitation "said absorbable barrier " in line 1. There is insufficient antecedent basis for this limitation in the claim. Correction is respectfully requested.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 14-16, 21, 24, 25, 28 and 31-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Isaji et al. (US 6,407,139) or Mori et al. (US 6,239,177) or Yamamoto et al. (US 5,356,620).

Isaji discloses composition comprising tranilast (abstract; column 2, lines 25-52; column 3, lines 22-24), additives such as excipients, disintegrators, binders, lubricants, diluents, buffers, isotonicity agents, antiseptics, moistening agents, emulsifiers, dispersing agents, stabilizing agents and dissolving aids (column 4, lines 34-39) and polymers such as lactic acid, polyacrylamide, lactic acid-glycolic acid copolymer and polyvinylpyrrolidone when a sustained

release preparation is desired (column 5, lines 1-7); the composition is formulated into dosage forms such as powders, granules, fine granules, dry syrup, tablets, ointments, injections and eye drops (column 4, lines 30-33) with ointment and eye drops representing non-systemic administration although the claimed invention is directed to a delivery device for which the composition of Isaji is. Claims 24, 25 and 31-33 are directed to the properties/characteristic of the device so that the composition of Isaji meets these claims. The polymers meet claims 16, 21 and the barrier of claim 14; the general composition taught by Isaji meets claims 14 and 28.

Mori discloses external tranilast composition (abstract; column 2, lines 39-43) comprising tranilast, dissolution medium (column3, line 54 to column 4, line 24), polymers such as propylene glycol (column 4, line 65), polyvinyl alcohol, polyethylene glycol, polyacrylate (column 5, lines 24-65); the composition of Mori and the polymer carrier meet the requirements of claims 14-16, 21 and 28. Claims 24, 25 and 31-33 are directed to the properties/characteristic of the device so that the composition of Mori meets these claims; the general composition of Mori meets claims 14 and 28.

Yamamoto discloses pharmaceutical composition containing tranilast (abstract), polyvinylpyrrolidone and surfactant (column 2, lines 32-64; columns 3 and 4), the composition meeting the requirements of the designated composition.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 14, 27-30, 34 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mori et al. (US 6,239,177 B1).

Mori is described above as describing the composition in claims 14-16, 21, 24, 25, 28 and 31-33. Mori describes that it has been found in the prior art that tranilast is found in the skin of keloid patients at about 8-10 μg/g (column 2, line 47) and suggests that tranilast concentration on skin after application to the skin would be higher that that previously observed (column 2, lines 57-60) but does not disclose the concentration of the tranilast in the composition. However, given the general teaching of Mori regarding the use of the tranilast to treat keloid or allergic dermatitis, one having ordinary skill in the art at the time the invention was made would have reasonable expectation of success in using an amount of the tranilast in the composition that would be effective to treat keloid or allergic dermatitis.

9. Claims 14, 22, 23, 40 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Isaji et al. , ("Tranilast: A New Application in the Cardiovascular Field a An

Antiprolferative Drug," in Cardiovascular Drug Reviews, Vol. 16, No. 3, pp. 288-299) in view of Akhtar et al. (US 5,432,163).

Isaji teaches that tranilast is an antiallergic drug, atopic dermatitis, allergic conjunctivitis, keloid fibroblast (pages 288-293; 295). Isaji does not teach the presence other therapeutic agents with the tranilast. However, Akhtar discloses antiproliferative for treating atopic dermatitis (column 3, lines 45-57). Given the general teachings of Isaji and Akhtar, one having ordinary skill in the art at the time the invention was made would have a reasonable expectation of success that the combined compositions of Akhtar and Isaji would be effective as an antiallergic drug, atopic dermatitis, allergic conjunctivitis, keloid fibroblast.

10. Claims 14, 22, 23, 40 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mori et al. (US 6,239,177 B1) in view of Pope et al. (US 5,948,822).

Mori has been described above for disclosing the composition in claims 14-16, 21, 24, 25, 28 and 31-33. Mori's composition does not contain further therapeutic agents. However, Pope discloses antiproliferative agent that reduces the hyperproliferative keloid formation (column 3, lines 12-34; column 5, lines 1, 2, 6 and 7). Given the general teachings of Mori and Pope, one having ordinary skill in the art at the time the invention was made would have a reasonable expectation of success that the combined compositions of Mori and Pope would be effective to reduce hyperproliferative keloid formation. See also *in re Kerkhoven.*

Double Patenting

11. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same

invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 14-19, 21-25, 27-37 and 39-41 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 14-41 of copending Application No. 10/714,719 (US 20050106229). This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

14. Claims 14-19, 21-25, 27-37 and 39-41 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 14-19, 21-24, 27-41 of copending Application No. 10/780,452 (US 20050181023) in view of Chandrasekar et al. ("Platelets and Restenosis," in Journal of the American College of Cardiology, Vo. 35, No. 2, 2000, pp 555-562) or Miyazawa et al. ("Effects of pemirolast and tranilast on intimal thickening after arterial injury in the rat," in Journal of Cardiovascular Pharmacology, Vol. 30, no. 2, Aug. 1997, abstract).

The compositions of copending claims 14-19, 21-24, 27-41 of application number 10/780,452 contain Pemirolast instead of Tranilast. Both the Pemirolast and the tranilast have the functionality of inhibiting post-operative adhesion. It is however known in the art that both tranilast and pemirolast are antiallergic agents known to reduce intimal thickening as disclosed by Chandrasekar (first full paragraph, left column of page 559) and Miyazawa (abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use pemirolast in place of tranilast with the expectation that the composition would reduce intimal thickening. One having ordinary skill in the art would have been motivated to use tranilast or pemirolast to reduce intimal thickening with the expectation to either would reduce intimal thickening.

This is a provisional obviousness-type double patenting rejection.

No claim is allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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